

Continual Improvement in Clinical Bacteriology Laboratory with Quality Indicators: A Retrospective Observational Study

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ABSTRACT

Introduction: Healthcare management is undergoing significant changes with the evolution of new and re-emerging infections. A clinical microbiologist plays an important role in giving an accurate and timely report to the clinicians. Quality Indicators (QIs) act as a measure of the quality of services offered by the laboratory and are tools to monitor and evaluate the laboratory's performance throughout the Total Testing Process (TTP).

Aim: To measure the performance of the clinical bacteriology laboratory using QIs.

Materials and Methods: A retrospective study was conducted in the Department of Microbiology at Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai, Maharashtra, India. The study evaluated QIs from the records of 94,624 samples received in the bacteriology section of the clinical Microbiology laboratory between January 2018 and March 2021. Data analysis was conducted over a six-month period from December 2021 to May 2022. In 2018, one QI was identified for each phase, with an additional QI added in each phase to the pre-existing QI in 2019. In 2020, a QI was added in the preanalytical phase only. In 2021, the acceptable limit

for one preanalytical QI was reduced from 2% to 1%. Data analysis was performed using an Excel sheet.

Results: Data from records of 94,624 clinical bacteriology samples collected over 39 months were analysed retrospectively. The preanalytical indicators included the number of samples rejected (135, 0.14%) and the number of requisition forms with three patient identifiers (59,645, 93.95%). Analytical phase QIs consisted of the average External Quality Assurance Scheme (EQAS) performance score (97.44% from January 2018 to March 2021) and outliers in the Internal Quality Control (IQC) (25 from January 2019 till March 2021). Failures in the IQC were not assessed in 2018. Postanalytical phase QIs included Turnaround Time (TAT) (average of 2.55 days for aerobic growth) and reporting time for critical alerts, which was within 24 hours of alert finding (100% for smear and culture-positive results).

Conclusion: Regular monitoring of QIs helps to identify potential errors. This laboratory chose to analyse and monitor its processes using practically feasible QIs. It was found that the laboratory consistently maintained its performance throughout the study period.

Keywords: External quality assurance scheme, Internal quality control failure, National accreditation board for testing and calibration laboratories

INTRODUCTION

Laboratory medicine plays a crucial role in diagnosing and monitoring patient outcomes [1]. Evaluating a laboratory's performance with evidence-based tools helps in ascertaining that patients receive safe and effective care [1,2]. Generating quality reports is of utmost importance as they directly impact patient care and outcomes [2]. Monitoring the testing process is quite challenging in resource-limited set-ups, especially those without access to automated techniques. QIs are simple and established measuring tools for continuous quality improvement which can be used even in these laboratories [2,3].

The study was conducted to highlight the importance of incorporating QIs as a routine measure for improving the quality of patient-related laboratory services. These indicators cover all three phases of the diagnostic cycle and are affected by factors related to the environment, humans, equipment, or procedures [4]. Hence, it is important that a robust quality management system is established [2,5,6].

In developed countries, accreditation is mandatory, whereas accreditation scheme in India is voluntary. The National Accreditation Board for Testing and Calibration Laboratories (NABL) authorises laboratories to establish its competence in carrying out specific scopes as per recommended standards. The benefits of accreditation go beyond the expenses of accreditation. The accreditation process helps reinforce quality among all stakeholders [7]. QIs are important tools that aid in error reduction [2,3,6,8,9].

The laboratory can define QIs at the start of the year and regularly analyse them to monitor laboratory services [3]. The aim of the study was to measure the performance of the clinical bacteriology laboratory using QIs. The primary objective was to define and monitor QIs in various testing phases. The secondary objective was to monitor the laboratory's contribution to patient care through accurate and timely report issuance, thereby improving laboratory services in the future.

MATERIALS AND METHODS

The study was a retrospective analysis of QIs in the bacteriology section of the Department of Microbiology at a tertiary care hospital in Mumbai (Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai). The study commenced after Institutional Ethics Committee (IEC) approval IEC/75/21 (dated 17.11.2021) in November 2021.

Inclusion criteria: All samples received in the bacteriology section of the Department of Microbiology were included in the study.

Exclusion criteria: Samples received in sections other than the bacteriology section of the Department of Microbiology were excluded from the study.

The records of 94,624 clinical bacteriology samples were collected over a period of 39 months (from January 2018 to March 2021) were analysed over a six-month period from December 2021 to May 2022. The clinical microbiology laboratory of this hospital is an NABL-accredited laboratory.

The QIs were categorised into preanalytical, analytical, and postanalytical QIs. In 2018, one QI was identified for each phase. In 2019, one additional QI was added to each phase alongside the pre-existing QI. In 2020, one QI was added in the preanalytical phase only. In 2021, the acceptable limit for one of the preanalytical QIs was reduced from 2% to 1%, while the other QIs remained the same as in 2020. The indicators and their acceptable limits were decided by the laboratory director in accordance with ISO 15189:2012 and NABL 112 guidelines [1-3,8].

a) Preanalytic phase QIs:

- Number of samples rejected (as per the sample rejection criteria) [Table/Fig-1];
- Presence of three patient identifiers on the laboratory requisition form (Patient's name, registration number-IPD/OPD, identity of the discipline and treating clinician from whom the patient was referred).
- Percentage of rejected samples that were inappropriate for culture, indicating poor sample quality sent for testing.

| |
|---|
| • No requisition form/test not mentioned |
| • Soiled requisition form |
| • Unlabelled samples |
| • Label on form and sample not matching |
| • No signature of clinician on the requisition form/no consent of patient on form |
| • Single form with multiple tests requested |
| • Requisition forms received but no sample |
| • Specimens received without a request form |
| • Leaking sample |
| • Insufficient quantity of sample |
| • Inappropriate sample (quality of sample) |
| • Repeat sample on the same day (unless telephonically requested) |
| • Delay in sample transport |

[Table/Fig-1]: Criteria for sample rejection (as per the Standard operating procedures manual).

| Primary smears positive | Culture positive |
|--|--|
| Sterile body fluids showing organisms | Sterile body fluids showing growth in absence of positive finding in primary smear |
| Stool for hanging drop showing darting motility suggestive of <i>Vibrio</i> species | Throat swabs from suspected cases of Diphtheria which are negative on primary smear but show growth on culture media (Potassium tellurite agar and Loeffler's serum slope) |
| Throat swabs showing organisms morphologically resembling <i>Corynebacterium</i> species (Grams stain as well as Albert stain) | Conventional blood cultures showing growth of gram negative bacilli or gram positive cocci (suspected <i>S. pneumoniae</i>) on culture |
| Samples from suspected cases of gas gangrene showing organisms morphologically resembling <i>Clostridium</i> species | Isolation of <i>Salmonella</i> species from any clinical specimen |
| Automated blood cultures (BacT/Alert 3D system) showing gram negative bacilli and gram positive cocci in pairs (lanceolate shape) on primary smear | Isolation of <i>Shigella</i> species or <i>Vibrio</i> species from stool specimen |
| | Isolation of Vancomycin Resistant Enterococci (VRE)/Vancomycin-Intermediate <i>Staphylococcus aureus</i> /Vancomycin Resistant <i>Staphylococcus aureus</i> (VISA/VRSA)/Carbapenem resistant gram negative bacteria from samples |

[Table/Fig-2]: Critical alerts for Critical Value (CV) reporting for bacteriology section (As per the SOPM of the Department).

| Acceptable limit of Quality Indicators (QI)/Years | Sample rejection | Patient identifiers (presence of 3 identifiers) | EQAS | Outliers in the internal quality check | Turnaround Time (TAT) | Critical alert reporting |
|---|------------------|---|---|--|---|---------------------------------|
| 2018 | ≤2% | NA | Excellent=≥80%; Good=79-60%; Satisfactory=59-50%; Below average=≤49% | NA | Aerobic culture with AST- upto 5 days; Anaerobic culture identification- upto 7 days; Blood culture (No growth)- till 7 days | NA |
| 2019 | ≤2% | 3 identifiers=75-100%, Only 2 identifiers=5-25%, Only 1 identifier=0-5% | Same as above | ≤20/year | Same as above | Reported with 24 hours of alert |
| 2020 | ≤2% | Same as above | Same as above | ≤20/year | Same as above | Same as above |
| 2021 (Jan to March) | ≤1% (↓) | Same as above | Same as above | ≤10% | Same as above | Same as above |

[Table/Fig-3]: Acceptable limit for the Quality Indicators (QI) of this laboratory (As per the SOPM of department).
Downward arrow indicates that the acceptable limit for rejection rate has been decreased from 2% to 1% in 2021 by the laboratory

b) Analytic phase QIs:

- Performance in External Quality Assurance Scheme (EQAS).
- Number of outliers/failures in the Internal Quality Controls (IQC) tested.

c) Postanalytic phase QIs:

- Average turnaround time for report generation.
- Reporting time of critical alerts to the clinician [Table/Fig-2].

An analysis of the QIs for the 94,624 clinical bacteriology samples, collected and sent by clinicians to the Department of Microbiology over a 39-month period (from January 2018 to March 2021), was done using an Excel sheet. The study was time-bound, considering all clinical samples received from patients during this period. The acceptable limits for the QIs are shown in [Table/Fig-3]. The grading and scoring are decided by this laboratory and are outlined in the Standard Operating Procedure (SOP) of the present laboratory.

The details of the selected QIs are as follows:

a) Preanalytical phase QIs:

- Number of samples rejected:** The rejection rate reflects the preanalytical workflow of the laboratory [2,10]. Clinical specimens are rejected if they do not meet predefined criteria [Table/Fig-1]. If a specimen is rejected, the treating clinician/nurse is informed telephonically, and a sample rejection form is signed and sent to the treating clinician. In special circumstances, samples falling under rejection criteria may need to be processed due to difficulty in repeating them [11]. Such precious samples include Cerebrospinal Fluid (CSF), intraoperative fluid/tissue/swab, blood cultures, and postmortem specimens.

This QI was implemented since January 2018 to March 2021. The number of rejected samples in a month, out of the total samples received in the laboratory for that month, was calculated and documented as a percentage (%). Starting from 2021, authors challenged themselves to reduce the rejection rate to less than 1% [Table/Fig-3].

- ii. **Patient identifiers:** Patient identifiers are unique and unchanging attributes. Globally, various patient identification techniques are used, ranging from Unique Patient Identifiers (UPIs) and algorithms to newer approaches like referential matching, biometrics, and Radio Frequency Identification Device (RFID) [12]. In this tertiary care hospital, the identifiers available on the sample requisition form were employed. As we lacked the Hospital/Laboratory Information System (HIS/LIS), we had to restrict ourselves to these identifiers. This QI was incorporated from January 2019 to March 2021.
 - iii. **Percentage of rejected samples that were inappropriate for culture:** This identifier was added in 2020 to the existing two indicators in the preanalytical phase. The inappropriate samples for culture that were rejected are as follows [11]:
 - Foley's tip for culture
 - Urine sample from a urobag
 - Samples received in unsterile containers
 - Samples sent in formalin
 - Leaky containers
 - Dry swabs
 - Urine samples that are not freshly collected
 - Tracheal swabs
- b) Analytic phase QIs:
- i. **EQAS program:** The EQAS program is a part of quality improvement for a laboratory. It reflects the quality of patient specimen testing in a clinical laboratory [13]. For the bacteriology laboratory, the Department of Microbiology, Christian Medical College (CMC), Vellore, is the EQAS laboratory recognised by the Indian Association of Microbiologists (IAMM). In each EQAS cycle, three unstained smears for staining and interpretation and three unlabeled cultures for identification and Antibiotic Sensitivity Test (AST) are provided. The tests carried out in the bacteriology laboratory are qualitative in nature. The score criteria were decided by the apex laboratory as:
 - Excellent: $\geq 80\%$
 - Good: 79-60%
 - Satisfactory: 59-50%
 - Below average: $\leq 49\%$
 This QI was incorporated from January 2018 to March 2021 with a year-wise scoring system.
 - ii. **Inter Laboratory Comparison (ILC):** ILC helps evaluate the performance of laboratories for specific tests and monitor the laboratory's performance if a laboratory does not have an EQAS program [14]. Since the bacteriology laboratory was under the EQAS program, an ILC was not required, and this QI was not evaluated.
 - iii. **Number of outliers/failures in the Internal Quality Controls (IQC) tested:** The isolation of microbial pathogens from clinical samples and their identification are carried out on culture media, biochemical tests, and staining techniques. Most of these media and reagents are prepared in the laboratory in batches.

Every newly prepared batch was only put into use after approval with the help of positive and negative culture controls. If any media/biochemical/reagent fails the quality check, the batch cannot be validated and hence is discarded [15]. The number of failed tests is documented as outliers, and corrective actions are taken after reviewing the processes. This QI was added from January 2019 onwards.
- c) Postanalytical phase QIs:
- i. **Turnaround Time (TAT):** TAT is one of the most observed parameters of laboratory service [16]. Many laboratories restrict their TAT to intralaboratory activities only [16]. The TAT for this laboratory was calculated as the time between the receipt of the sample in the laboratory and the reporting time (days for cultures). This QI was calculated annually from 2018 onwards. The acceptable time period for TAT for reports of bacterial cultures, as defined in the SOP manual, is as follows: aerobic culture with AST up to five days; blood culture (No growth) up to seven days.
 - ii. **Critical Value (CV) reporting:** Critical alerts are laboratory results that require prompt communication to the treating physician to avert potential serious outcomes [17]. They refer to the presence of microorganisms (on smear and/or culture) that requiring prompt patient isolation and/or public notification. The advisable means of CV communication is internal phone calls. All critical alerts, as mentioned in [Table/Fig-2], are informed from the laboratory to the treating physician/nurse within 24 hours as per the SOPM. Critical alerts are documented in the following manner (for both primary smear and culture):
 1. The treating physician/nurse is called on the landline number;
 2. The patient's identity is confirmed by at least two patient identifiers (Name and registration number);
 3. The requested laboratory test is confirmed;
 4. The critical alert is informed;
 5. The treating physician/nurse is asked for read-back confirmation;
 6. The details are documented;
 7. If the clinician/nurse has difficulty in reading back the critical alert, then the laboratory personnel repeat the critical alert finding with the patient details and ask for a read-back confirmation again.
- The data for the QIs were collected in this laboratory every three months and reviewed annually during internal audits and management review meetings. Most of the QIs were expressed in the results as percentages. Indicators like IQC outliers were expressed as absolute numbers annually until 2020. However, from 2021 onwards, they were also expressed as a percentage of outliers among the total tests done.

RESULTS

During the 39-month study period, a total of 94,624 clinical bacteriology samples were received in the bacteriology laboratory. The samples were collected by the resident medical officers of the respective clinical disciplines. [Table/Fig-4] shows the QIs in the preanalytical phase from 2018 to March 2021. The number of rejected samples was 135 (0.14%). Approximately, 59,645 out of 63,481 requisition forms (93.95%) had all three defined patient identifiers. Out of the total rejected samples, 17 out of 38 (44.73%) were inappropriate for culture. The EQAS performance of the bacteriology laboratory, as per the reports, was excellent in all the years from 2018 to 2021 ($\geq 80\%$). As observed in [Table/Fig-5], though the laboratory scored less in the December 2020 cycle, the average score from 2018 to March 2021 was 97.44%. For 2019 and 2020, the IQC outliers were nine and 13, respectively, for the batches of media prepared. During the NABL assessment of the laboratory in 2021, it was suggested by the assessors to display the outliers as a percentage. The suggestion was incorporated subsequently from 2021 onwards. For the year 2021 (January to March), IQC failed in 3 batches out of the 743 batches of media prepared and tested (0.40%). In the postanalytical phase, the

| Year | Samples received (n=94624) | Samples rejection rate | Requisition forms with three identifiers (%) (n=63481) | Rejection based on quality of sample out of the total rejected samples (%) (n=38) |
|-------------------------|----------------------------|------------------------|--|---|
| 2018 | 31143 | 50 (0.16%) | Not applicable | Not applicable |
| 2019 | 33905 | 47 (0.14%) | 31915 (94.13%) | Not applicable |
| 2020 | 22607 | 27 (0.12%) | 21447 (94.87%) | 11 (40.74%) |
| 2021 (January to March) | 6969 | 11 (0.16%) | 6283 (90.16%) | 6 (54.54%) |
| Total | 94624 | 135 (0.14%) | *59645 (93.95%) (out of 63481 samples) | 17 (44.73%) |

[Table/Fig-4]: Quality Indicators (QI) in preanalytical phase.

*The requisition forms are hand-written by the resident medical officers. In the morning rush hours, some details might have missed to be written. Hence, not all requisition forms have all three identifiers.)

average TAT for issuing reports of growth positive aerobic cultures was 2.55 days. [Table/Fig-6] illustrates the TAT for issuing reports for growth positive cultures and sterile blood cultures (conventional/automated techniques).

| EQAS cycle (Month/year) | *Score for smears | *Score for culture identification with AST | Score of the laboratory | Average score |
|-------------------------|-------------------|--|-------------------------|---------------|
| March 2018 | 12/12 | 49/49 | 61/61 (100%) | 2018 (98.36%) |
| June 2018 | 9/12 | 49/49 | 58/61 (95.08%) | |
| October 2018 | 12/12 | 49/49 | 61/61 (100%) | |
| March 2019 | 12/12 | 54.5/55 | 66.5/67 (99.25%) | 2019 (97.06%) |
| June 2019 | 11.5/12 | 53/53 | 64.5/65 (99.23%) | |
| October 2019 | 10/12 | 47/49 | 57/61 (93.44%) | |
| March 2020 | 11.5/12 | 49/49 | 60.5/61 (99.18%) | 2020 (94.37%) |
| August 2020 | 8/8* | 48/49 | 56/57 (98.24%) | |
| December 2020 | 12/12 | 38/47 | 50/59 (84.74%) | |
| February 2021 | 8/8* | 47/47 | 55/55 (100%) | 2021 (100%) |
| Average score | | | 97.44% | |

[Table/Fig-5]: EQAS score of the bacteriology laboratory (QI of the analytic phase).

*One smear result was removed from evaluation for all participating laboratories

*Score for smear=4 marks per smear

*Score for culture ID=7 marks and AST=2 marks per antibiotic disc tested

| Year | Growth (days) | Sterile blood cultures (days) |
|---------------------------|---------------|-------------------------------|
| 2018 | 2.66 | 4.29 |
| 2019 | 2.75 | 4.23 |
| 2020 | 2.70 | 4.52 |
| 2021 (January-March) | 2.07 | 2.88 |
| Average TAT (days) | 2.545 | 3.98 |

[Table/Fig-6]: Turnaround Time (TAT) for the bacteriology laboratory.

The critical alerts were informed telephonically to the clinicians to help them in establishing a definitive diagnosis and subsequent management. From 2019 till March 2021, there were a total of 128 primary smears reported as critical alerts to physicians, whereas the culture-positive samples that qualify as critical alerts were 1538 (1318 from blood culture samples and 220 from cultures of other samples). The clinicians were informed each year within 24 hours about the primary smear alert or culture alert wherever applicable.

DISCUSSION

Laboratory quality depicts the accuracy, reliability, and timeliness of the reported test results. The maintenance of quality is a multifaceted task that requires detection of poor performance in various modalities of laboratory activity with the help of indicators [18]. Consistent planning and monitoring of quality with the help of indicators result in continual quality improvement [1,2,15,18]. The definition of the performance specifications for each indicator in terms of limits of acceptability facilitates the interpretation of results of QIs and can help identify the steps for corrective actions [1,18].

Errors in the preanalytical phase generally occur from high personnel turnover rates, negligence, and lack of adequate training [4]. These errors result in inconvenience for both patients and clinicians, thereby

decreasing confidence in the results issued by the laboratory [4,15]. Sample rejection can be used as a quality indicator for the continual improvement of laboratory services [19]. A meta-analysis by Getawa S et al., reported the blood specimen rejection rate as 1.99% [10]. Khumalo S reported a rejection rate of 8% for the microbiology laboratory that handled samples from community health centres [20]. Soni S et al., reported a similar rejection rate (0.11%) to that of this study (0.14%). They reinforced the importance of regular training for clinicians and nurses regarding sample collection and transport. They also reported a reduction in the sample rejection rate post-training (0.11%) compared to pretraining (0.31%) [19]. Such an analysis was not carried out in this study. There was a drastic decrease in the sample size in 2020 as the total number of samples received during the Coronavirus Disease-2019 (COVID-19) pandemic was comparatively less as compared to previous two years, but the rejection rate remained within acceptable limits. Unique Patient Identifiers (UPIs) are widely implemented and preferred methods of patient identification in Europe, China, New Zealand, and Israel. Other methods of patient identification can include algorithmic approaches like the use of first name, last name, age, date of birth, and social security number. The algorithm matching rate can approach approximately 90%, but they are not perfect and do not represent 100% accurate patient matching [12]. Present study did not include any UPIs or algorithms. Only basic data (name, registration number, and treating facility) as mentioned on the requisition was used. The patient identification rate for all three identifiers was 93.95%. This laboratory faced challenge with respect to receipt of good quality samples. Although regular training programs are organised for resident doctors with respect to correct method of sample collection, the compliance of the residents in these training programs is not always 100% due to reasons such as emergency duties, rotational duties in wards and Intensive Care Unit (ICUs), casualty, OPD, etc. Approximately 45% of the rejected samples were not of good quality. Rejection of samples due to poor quality leads to wastage of resources as well as inconvenience to patients. Strategies to improve compliance after training need to be developed. Additionally, effective communication between the laboratory and clinical staff can ensure the receipt of good quality samples to the laboratory, as highlighted by Soni S et al., [19].

Despite a shortage of staff and an increasing workload and academic commitments, we were convinced that the first two QIs in the preanalytical phase were well maintained. Internal Quality Control (IQC) and External Quality Assessment Schemes (EQAS) are well known indicators of the analytical process in laboratory medicine [18]. The analytical phase QIs were under direct supervision by the faculty, as any breach in practices would severely hamper patient results. In addition, there was continuous monitoring and regular competency assessment to monitor the performance of laboratory technicians, as also discussed by Kulkarni S et al., [5]. Regarding EQAS, as a rule of thumb, if the laboratory results are lower than a set-point (usually 80%), the laboratory's performance for that test is poor and should avoid further execution of the test in clinical samples until cleared [15]. The EQAS performance for the bacteriology laboratory had been consistently excellent ($\geq 80\%$).

The EQAS results for the bacteriology laboratory are qualitative in nature, unlike most parameters in the microbiology laboratory. Sekar K have reported an error acceptance rate of 5% in EQAS for the Microbiology laboratory [2]. In a literature review, Ricós C et al., reported an error rate of 1.4% as an unacceptable result of proficiency testing for the pathology laboratory [18]. The EQAS program can be a valuable management tool to enhance laboratory services [13]. The main objective of quality control in a laboratory is to ensure the consistency of an analytical process so as to ensure that reliable reports are issued to patients [21]. The errors in IQC reported as a result of human errors while preparation of media can result in the failure. The IQC outlier for 2021 was 0.40%. In their literature review, Ricós C et al., reported an error rate of 0.07% in an automated pathology laboratory [18]. The errors monitored in the analytical phase in this study were unacceptable EQAS performance and IQC outliers. Although all EQAS cycles had excellent scores, one cycle had a score close to the acceptable limit. As a preventive measure, the staff was retrained. The use of automated methods can help reduce manual errors and TAT. However, automated techniques in this municipal hospital are currently reserved only for critically ill patients due to resource constraints.

An important factor affecting quality in the postanalytical phase is effective communication between the laboratory and the treating physician. Plebani M et al., have commented that the use of automation techniques, electronic results reporting, and electronic alerting systems can significantly reduce the time required for report generation [1]. Many laboratories restrict their TAT to intralaboratory activities only since factors outside the laboratory are beyond their control [2,16]. Delays in TAT result in immediate complaints from users [16]. This hospital does not have a Hospital Information System (HIS). The average TAT for issuing reports of growth-positive aerobic cultures was 2.55 days. Sekar K defined TAT for samples for culture and sensitivity as 48-72 hours [2]. Timely reporting of Critical Values (CVs) directly impacts patient management, the effective control of nosocomial outbreaks, and the early detection of microorganisms with unusual phenotypical traits (such as Multidrug Resistance) [22,23]. Studies have reported the frequency of reporting CVs from one in 100 to 1 in 2,000 samples [22,24]. This study reported 1538 critical alerts. Passerini R et al., reported a total of 150 microbiological alerts from May 2006 to September 2008 [23]. Their study also highlighted the use of an automated surveillance system as a positive choice, both for the standardisation of alert extraction criteria and for timely data reporting to clinicians. The laboratory maintained the postanalytical QIs within the acceptable limit of the laboratory. Strategies for strengthening the HIS in a municipally run hospital like ours are of utmost importance. Quality is an ongoing dynamic process. The QIs in the laboratory should be designed in a way that helps evaluate and improve the healthcare delivery system. The indicators should be easy to implement, quantifiable, and scientifically correct [25]. The QIs guided the laboratory to evaluate the proficiency of the laboratory workers and helped to take corrective/preventive actions wherever required. This hospital is one of the major Municipal Corporation hospitals in Mumbai with a heavy patient load and a high turnover of samples. Despite the limited use of automated techniques, the number of rejected samples in the preanalytical phase showed continual improvement. Other QIs were maintained within an acceptable range.

Limitation(s)

Lack of automated techniques for sample accession, testing, and data collection; Preparation of all media in-house increasing the scope of human errors; Paucity of trained clinical staff like resident medical officers due to frequent rotation of postings.

CONCLUSION(S)

Continuous monitoring of QIs helps to identify potential errors. This laboratory chose to analyse and monitor its processes using practical and feasible QIs. It was found that the laboratory maintained its performance consistently throughout the study period. The preanalytical QI regarding the number of samples rejected showed continual improvement, even though the processes were beyond the control of the laboratory. The laboratory would like to compare its processes with others using these QIs in order to reach the benchmark of providing the best patient care services.

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